

Claims 1-3 and 7-8 stand rejected under 35 USC §102(b) as being anticipated by WO95/01842. Applicants respectively traverse this rejection of the Examiner. Applicants' claim 1 as amended requires that the step of transferring the enriched fraction through the outlet tube occurs upon activation of the valve into an open position during centrifugation. WO95/01842 does not specifically disclose activation of a valve into an open position during centrifugation. WO95/01842 also does not disclose activation of a valve into an open position during centrifugation to transfer an enriched fraction. This feature is not anticipated by WO95/01842 and thus the international application does not disclose every feature as set forth in Applicants' claims as required for anticipation. Applicants therefore ask the Examiner to reconsider this rejection of claim 1.

Claim 2 has been cancelled by Applicants. With respect to claim 3, Applicants note that the buffy coat embodiment in WO95/01842 does not disclose any valving. Therefore, with respect to claim 3, Applicants ask the Examiner to also reconsider his rejection under 35 USC §102(b) both for the reasons set forth with respect to claim 1 and also because WO95/01842 does not specifically disclose valves with its buffy coat embodiment.

As to claims 7 and 8, it is Applicants' position that these claims should be allowed for the reasons set forth above with respect to claim 1. Also WO95/01842 does not specifically disclose a stem cell or red blood cell embodiment.

Claims 9-11, (note: the rejection states 9-12 but claim 12 was withdrawn from consideration), stand rejected by the Examiner under 35 USC §103(a) as being unpatentable over WO95/01842. The Examiner is asked to reconsider this rejection under 35 USC §103(a) for the reasons set forth with respect to claim 1 above from which these claims depend. Also, with respect to claim 9, it is Applicants' position that WO95/01842 does not specifically disclose a manually activatable clamp. Also with respect to claim 10, the reference cited by the Examiner does not specifically disclose a magnetically activatable valve nor does it disclose an electromagnetically activatable valve (claim 11). The Examiner has cited no examples of manual clamps or magnetic or electromagnetically activated valves nor has he cited any examples of such clamps/valves associated with an outlet tube as set forth in Applicants' claim 1. There is no teaching of using such types of clamp/valves with the apparatus of the cited reference. Thus, it is

Applicants' position that claims 9, 10, and 11 are not made obvious by the WO95/01842 reference.

Claims 4-6 stand rejected under 35 USC §103(a) as being unpatentable over WO95/01842 in view of Kellogg et al under 35 USC §103(a). Claims 4-6, which depend from claim 1, should be patentable for the reasons set forth with respect to claim 1. In addition, there is no teaching of combining the separation system of Kellogg et al with the separation system of WO95/01842. Also, even it were obvious to combine the teachings of Kellogg et al with WO95/01842, such a combination would not yield Applicants' claimed invention. For example, WO95/01842 is different for the reasons set forth with respect to claim 1 above. Also, neither the WO95/01842 reference nor Kellogg discloses the step of "diverting said radial flow into a peripheral flow via a cell trap having an enlarged section." In Kellogg, cell trap 17 is at one end of the channel 11. Tubes 21 and 19 are outlet tubes, not inlet tubes at the same end of the channel. Thus Kellogg does not disclose "diverting ... via a cell trap" since the cell trap 17 is at the outlet end of the channel.

Note also that WO95/01842 has only one outlet tube 3 and that in the device of the reference lighter phase is pressed out of the outer bag. Kellogg, in contrast, is directed to a system where flow and the position of the outlet tubes with respect to the collection areas determine the withdrawal of the separated fraction. In conclusion, it is Applicants' position that it would not be obvious to combine the diverse separation teachings of Kellogg with WO95/01842, and even if combined such a combination would not yield the diverting step of claim 4. Also neither reference discloses activation of the valve during centrifugation as set forth in claim 1.

In view of the arguments presented above Applicants ask the Examiner to reconsider his rejection of claims 4-6 as unpatentable over WO95/01842 in view of Kellogg.

#### REMARKS REGARDING INFORMATION DISCLOSURE STATEMENT

The Office Action Summary (PTO-326) mailed October 23, 2002 (Paper Number 5) has no indication that Applicants' Information Disclosure Statement (IDS) had been received by the USPTO. Applicants hereby wishes to bring the Examiner's attention to the following facts:

Applicants mailed the Information Disclosure Statement to the USPTO on January 15, 2001. The USPTO's Office of Initial Patent Examination (OIPE) acknowledged the receipt of the IDS package by having stamped and returned the postcard. Furthermore, the File Contents History posted on the USPTO's Patent Application Information Retrieval (PAIR) for this application has listed number 5 as "Information Disclosure Statement (IDS) filed" with the date of "01-15-2002". (Attachment 1, printout of the PAIR File Contents History for Serial Number 09/978428)

Based on the above-mentioned facts, Applicants hereby respectfully request the Examiner to consider the IDS filed by the Applicants on January 15, 2002 and initial the references cited.

In addition, Applicants also would like to point out the fact that the following references cited by the Examiner in PTO-892 Notice of References Cited had already been cited by Applicants in the IDS filed by the Applicants on January 15, 2002. They are:

|           |         |                 |
|-----------|---------|-----------------|
| 4,010,894 | 3/1977  | Kellogg et al.  |
| 4,990,132 | 2/1991  | Unger et al     |
| 5,114,396 | 5/1992  | Unger et al.    |
| 5,160,310 | 11/1992 | Yhland          |
| 5,316,540 | 5/1994  | McMannis et al. |
| 5,674,173 | 10/1997 | Hlavinka et al. |
| 87/06857  | 11/1987 | WO              |
| 95/01842  | 1/1995  | WO              |

\* \* \*

In view of the foregoing remarks, the rejections presented in the Office Action of October 23, 2002 have hereby been fully obviated/traversed, and can thus be withdrawn. Action to this end is respectfully requested so that claims 1 and 3-11 may then be fully examined, allowed, and passed to issue.

It is believed that the fee for one-month extension of the period for filing this Response is \$110.00. Please charge deposit account 03-2316 for this due amount. If any other fee is

determined to be necessary, the Commissioner is authorized to charge the above-identified account.

If there are any questions, or if prosecution can be expedited in any manner by a telephonic conference, the Examiner is urged to call the undersigned at the below-printed telephone number.

Respectfully submitted,

2/24/03

Date

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Attachment

**Marked-up Version of Claim Cancellations and Amendments Showing Changes Made**

What is claimed is:

1. A method of separating cells in a centrifuge comprising:  
providing a cell suspension in a processing bag;  
separating the cells suspension in the processing bag into a fraction enriched with specific cells by centrifugation in a centrifuge;  
transferring the enriched fraction to a storage bag via an outlet tube;  
adapting said outlet tube in a position having a radially inwardly directed flow and having a valve associated therewith;  
whereby said step of transferring said enriched fraction through said outlet tube occurs upon activation of said valve into open position during centrifugation.

~~2. A method according to Claim 1 in which said activation of said valve into open position occurs during centrifugation.~~

3. A method according to Claim 1 in which said cell suspension includes a buffy coat and said enriched fraction is a light-weight fraction enriched with platelets.

4. A method according to Claim 1 in which the transferring of said enriched fraction ~~through a first radially positioned portion of~~ via said outlet tube ~~having a radially inwardly directed flow~~ includes diverting said radial flow into a peripheral flow via a cell trap having an enlarged section for maintaining specific cells.

5. A method according to Claim 1 in which the transferring of said enriched fraction through said outlet tube includes transferring through at least one enlargement formed in said outlet tube for separation of more dense cells.

6. A method according to Claim 1 in which the transferring of said enriched fraction ~~through~~ via ~~a first radially positioned portion of~~ said outlet tube ~~having a radially inwardly~~

~~directed flow~~ includes flowing through said valve and through a ~~second~~ radially positioned portion of said outlet tube having a radially outwardly directed flow.

7. A method according to Claim 1 in which said cells are platelets or stem cells.
8. A method according to Claim 1 in which said cells are red blood cells.
9. A method according to Claim 1 in which said valve is a manually activatable clamp.
10. A method according to Claim 1 in which said valve is a magnetically activatable valve.
11. A method according to Claim 1 in which said valve is an electromagnetically activatable valve.
- ~~12. A bag assembly for separation of cells in a centrifuge comprising:  
—— a processing bag intended to contain a cell suspension and to be placed in a centrifuge for separating the cells into a fraction enriched with specific cells by centrifugation;  
—— a storage bag; and  
—— an outlet tube for transferring said enriched fraction to the storage bag;  
—— whereby said outlet tube is adapted to be placed in a position having a radially inwardly directed flow and adapted to be engaged by a clamping member on said centrifuge which provides for transferring said enriched fraction through said outlet tube upon activation of said valve to open position.~~
- ~~13. A bag assembly according to Claim 12 in which said outlet tube is adapted to be engaged by said valve and activated into open position during centrifugation.~~
- ~~14. A bag assembly according to Claim 12 in which said outlet tube comprises a chamber forming an enlargement at the outlet tube.~~

~~15. A bag assembly according to Claim 12 in which said outlet tube is provided with spaces having stagnant flow.~~

~~16. A bag assembly according to Claim 12 in which said cells are platelets or stem cells.~~

~~17. A bag assembly according to Claim 12 in which said cells are red blood cells.~~

~~18. A bag assembly according to Claim 12 in which said clamping member is a manually activatable clamp.~~

~~19. A bag assembly according to Claim 12 in which said clamping member is a magnetically activatable valve.~~

~~20. A system for separation of cells comprising:~~

~~a centrifuge device; and~~

~~a bag assembly which is adapted to be disposed in said centrifuge, said bag assembly including:~~

~~a processing bag intended to contain a cell suspension and to be placed in a centrifuge for separating the cells into a fraction enriched with specific cells by centrifugation;~~

~~a storage bag; and~~

~~an outlet tube for transferring said enriched fraction to the storage bag;~~

~~whereby said outlet tube is adapted to be placed in a position having a radially inwardly directed flow and adapted to be engaged by a clamping member on said centrifuge which provides for transferring said enriched fraction through said outlet tube upon activation of said valve to open position.~~



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## Search results for application number: 09/978,428

|                            |                    |                         |                                  |
|----------------------------|--------------------|-------------------------|----------------------------------|
| Filing or 371(c) Date:     | 10-15-2001         | Class / Sub-Class:      | 494/045.000                      |
| Issue Date of Patent:      | -                  | Location:               | TC 1700 CENTRAL FILES, CP3-10C24 |
| Examiner Name:             | KIM, SUN U         | Status:                 | Non Final Action Mailed          |
| Group Art Unit:            | 1723               | Attorney Docket Number: | B0048-US02                       |
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## File Contents History

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| 12     | 10-23-2002 | Mail Non-Final Rejection                     |
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| 5      | 01-15-2002 | Information Disclosure Statement (IDS) Filed |
| 4      | 10-30-2001 | Application Dispatched from OIPE             |
| 3      | 10-26-2001 | Correspondence Address Change                |
| 2      | 10-24-2001 | Application Scanned                          |
| 1      | 10-15-2001 | Initial Exam Team nn                         |

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